



POPP
USSN 10/617,191

PATENT
Attorney Docket No. 24948

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

POPP

Examiner: L. Channavajjala

Serial No.: 10/617,191

Art Unit: 1615

Filed: July 11, 2003

For: **TOPICAL FORMULATIONS FOR TREATMENT OF SKIN DISORDERS**

Appendix A

Claim Amendments

Please amend the claims according to the following "marked-up" copy of the claims:

1 - 25. (Cancelled)

26. (Currently Amended) A process for preparing a storage-stable topical composition for treating for a skin disorder or condition, which comprises the steps of:

a) forming at a temperature of about 15 to about 25 °C a benzoyl peroxide intermediate dispersion ~~having between about 5.9% and about 7.2% benzoyl peroxide and~~ having a viscosity of about 60,000 to about 250,000 centipoises sufficient to yield a composition which contains between about 2.25% and about 12.5% by weight benzoyl peroxide in the final product;

b) forming at a temperature of about 15 to about 25 °C a clindamycin intermediate solution sufficient to yield a composition which contains between about 0.5% and about 1.5% by weight clindamycin active in the final product; and

c) mixing said benzoyl peroxide intermediate dispersion and said

clindamycin intermediate solution under conditions sufficient to yield a benzoyl peroxide and clindamycin mixture having final pH of between about 4.5 to about 5.0, wherein said mixture has a viscosity lower than the viscosity of the benzoyl peroxide intermediate dispersion, wherein the viscosity of the mixture is of about 50,000 to about 200,000 centipoises, and wherein said composition comprises sufficient inactive ingredients to provide storage stability and effectiveness for a treatment period.

27. (Original) The process of claim 26, wherein said process results in a composition having benzoyl peroxide impurities of not more than about 0.01% by weight.

28. (Original) The process of claim 26, wherein said process results in a composition having clindamycin degradates of not more than about 0.02% by weight.

29. (Original) The process of claim 26, wherein said process results in a composition having benzoyl peroxide impurities of not more than about 0.01% by weight and clindamycin degradates of not more than about 0.02% by weight.

30. (Original) The process of claim 26, wherein said mixture has a final pH of between about 4.6 to about 4.8.

31. (Original) The process of claim 26, wherein said composition has less water by weight as compared to a topical formulation having one of benzoyl peroxide or clindamycin but not both.

32 – 37. (Cancelled)